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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,542	12/11/2002	Johan Auwerx	234/231	6461

7590 11/17/2005  
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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/463,542

Applicant(s)

AUWERX ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-11, 18 and 26-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-11, 18 and 26-33 is/are allowed.
- 6) ☒ Claim(s) 34-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/25/05, 6/20/05</u> | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to an amendment filed 8/24/05. Claims 1-8, 12-17 and 19-25 have been cancelled. Claims 9-11 and 18 have been amended. Claims 26-41 have been added. Claims 9-11, 18 and 26-41 are pending in the application.

#### ***Response to Amendment***

Any rejection of record in the previous action not addressed in this office action is withdrawn. The new grounds of rejection herein were necessitated by amendment and, therefore, this action is final.

#### ***Information Disclosure Statement***

IDS' filed 6/20/05 and 8/25/05 have been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

#### ***Claim Objections***

Claim 27 is objected to because of the following informalities: the term "β-lactamase" is incorrectly written as "p-lactamase". **This is a new objection necessitated by applicants' amendment.** Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

Claims 34-41 recite a genus of PPAR $\gamma$ 1, PPAR $\gamma$ 2 and PPAR $\gamma$ 3 nucleic acids that are control regions of a human peroxisome proliferators activated receptor gene.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The instant invention is drawn to control regions from peroxisome proliferator activated receptors (PPAR $\gamma$ ) gene. The PPAR $\gamma$  gene has nine exons and extends over more than 100 kilobases. By control regions, applicants intend elements associated with assisting or impeding, initiation, termination or otherwise regulating the transcription of the gene such as promoters, enhancers, silencers and other regulatory elements such as regulators of pausing or anti termination, which can be upstream, downstream or in introns or exons and involved in regulating translation such as splicing (page 5, paragraph 1-18). Applicants only exemplify the control regions from PPAR $\gamma$ 1, PPAR $\gamma$ 2 and PPAR $\gamma$ 3 genes that are found at the 5' end of the

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genes. These sequences were isolated and cloned, and presented respectively SEQ ID NO:s 1, 3 and 34 (see e.g. table III and page 7, line 2-page 8, line 27). Applicants teach that a variety of fragments obtained from these regions are preferred. Specifically, -125 to +196 and -3kb to +110 of the PPAR $\gamma$ 1 gene, -502 to +182 and -1kb to +122 of the PPAR $\gamma$ 2 gene and -777 to +74 and -800 to +1 of the PPAR $\gamma$ 3 gene. Therefore, the disclosure has taught the isolation and characterization of the promoter region from PPAR $\gamma$ 1, PPAR $\gamma$ 2 and PPAR $\gamma$ 3 that comprise all of the transcriptional elements within these sequences.

In claims 34-41, applicants recite a broad genus of fragments that encompass at least 100, 60 or 30 nucleotides from each promoter. However, applicants do not disclose the structural requirements such as those domains, regions or specific nucleotides of the control regions of PPAR $\gamma$ 1, PPAR $\gamma$ 2 and PPAR $\gamma$ 3 such that a person of skill in the art would know what fragments would themselves function as control regions. As guidance, applicants only disclose the following. There is not a TATA box in PPAR $\gamma$ 1; that in PPAR $\gamma$ 2 there is a TATA like element at -68 and a CAAT like consensus sequence at -56 and an AP-1 site at +10; in the PPAR $\gamma$ 3 promoter several consensus sequence elements were identified, a TATA element at -34, a CAAT like consensus sequence at -118 and a potential E-box at -342. However, it is unclear if these elements are sufficient for regulating the complex expression of PPAR $\gamma$  genes. Hence, the specification fails to convey the relevant identifying characteristics of the recited control regions nor provide a description of the control regions such that the structural requirements of the sequences can be envisioned other than for the three promoters. Therefore, there is no disclosure of a structure-function relationship between the sequence of SEQ ID NO 1, 3 or 34 and activity as a control region. Given the large size and diversity of fragments that comprise at least 100, 60

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or 30 nucleotides and the inability to determine which will also have the essential element, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of no species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

### ***Conclusion***

Claims 34-41 are rejected.

Claims 9-11, 18 and 26-33 are allowed.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1633

November 10, 2005

  
**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**